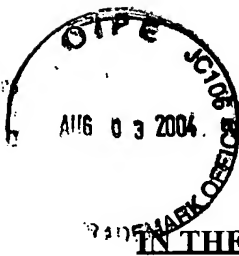


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 AF 1743
 EFW

PATENT
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:)	<u>CERTIFICATE OF MAILING</u>
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DAVID J. BEEBE ET AL.)	being deposited with the United States
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Serial No.: 10/045,937)	envelope addressed to: Mail Stop Box
)	Amendment - No Fee, Commissioner for
Filed: October 19, 2001)	Patents, P.O. Box 1450, Alexandria, VA
)	22231-1450 on <u>7-29-04</u> .
Examiner: Lyle Alexander)	
)	
Art Unit: 1743)	<u>Christine Kierzek</u>
)	
METHOD AND APPARATUS FOR)	<u>Christine Kierzek</u> <u>7-29-04</u>
MONITORING THE ENVIRONMENT)	Signature Date
WITHIN A MICROFLUIDIC DEVICE)	

REQUEST FOR RECONSIDERATION

Sir:

Responsive to the Office Action dated June 4, 2004, Applicant respectfully requests reconsideration in view of the following comments.

Initially, it is noted that the Examiner has rejected claims 1-27 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. More specifically, the Examiner has objected to the limitation "...wherein the first and second indicia are independent in size." In the Examiner's opinion, this limitation is vague and indefinite because the Examiner cannot ascertain the relationship between the indicia and the size. It is noted, however, that Applicant is specifically stating with such limitation that there is no relationship between the first and second indices and the size of the monitor structure. As such, it is believed that the limitation objected to by the Examiner is entirely appropriate. However, if the Examiner would offer suggested language that overcomes the objection, it would be greatly appreciated.

The Examiner has also objected claims 1-27 under 35 U.S.C. §102(e) as being clearly anticipated by Beebe et al., U.S. Patent No. 6,488,872. However, as hereinafter described, Applicant respectfully disagrees with the Examiner's conclusion and requests reconsideration in view of the following comments.

Claim 1 defines a microfluidic device for displaying indicia in response to a change in a predetermined parameter of a fluid flowing therethrough. The microfluidic device includes a body defining a channel for accommodating a flow of fluid therethrough. The monitor structure is retained in the channel of the body at a user selected position within the flow of fluid. The monitor structure displays a first indicia in response to the predetermined parameter of the fluid having a first value and a second indicia in response to the predetermined parameter of the fluid having a second value. The first and second indices are independent of size. In other words, there is no relationship between the first and second indices and the size of the monitor structure. As hereinafter described, nothing in the cited reference shows, suggests or anticipates a microfluidic device wherein the monitor structure is retained at a user desired position within a channel thereof where the indices displayed by the monitored structure are independent of the size of the monitor structure.

The Beebe et al., '872 patent is directed to a method of fabricating a microfluidic device. The method includes the steps of providing a cartridge defining a chamber filled with a polymerizable material. A photomask is positioned on top of the surface of the cartridge and the cartridge is exposed to ultraviolet light. The photomask corresponds to geometry of a channel network to be formed within the microfluidic device. When polymerization is complete, a residual of unpolymerized material is fed from the cartridge to provide the channel network therein. Thereafter, structural components may be formed in the channel utilizing the same process. As pointed out by the Examiner, one of such components includes a device that contains a responsive hydrogel. The hydrogel acts as a both a sensor and an actuator that increases or decreases in size in response to a physical change or chemical change within the

channel of the microfluidic device. The Examiner suggests that Column 34, lines 32-42 of the Beebe et al. '872 patent teach a change in optical properties in response to the detection of changes in pH. However, as hereinafter described, the monitor structure does not change optical properties as required by independent claim 1, and this change in optical properties is not independent of the size of the monitor structure.

Referring to Column 34, lines 33-42 of the Beebe et al., '872 patent, the structure described therein is vastly different than the structure defined in independent claim 1. The hydrogel sensor disclosed in the Beebe et al., '872 patent expands in response to a stimulus so as to prevent a dye from flowing therepast. In the absence of a stimulus, the hydrogel is in a contracted state such that the dye flowing past the hydrogel sensor is visible. As the hydrogel sensor expands in response to a stimulus, the sensor presses against the top internal surface of the device. As a result, dye can no longer flow past the hydrogel sensor and the hydrogel sensor appears to be of a different color. As described, the indices are directly dependent upon the size of the hydrogel sensor, in direct contrast to the limitations of independent claim 1. Further, unlike independent claim 1 wherein the monitor structure displays first and second indices, the hydrogel sensor merely prevents dye from flowing therepast so as to give the user the appearance of a color change of the device.

Since the Beebe et al. '872 patent does not provide for each and every limitation of independent claim 1, it is believed that claim 1 is not anticipated by the '872 patent. Claims 2-9 depend either directly from independent claim 1 and further define a microfluidic device not shown or suggested in the art. It is believed that claims 2-9 are allowable as depending from an allowable base claim and in view of the subject matter of each claim.

Claim 10 defines a method of monitoring the environment within a microfluidic device. The method includes the steps of immobilizing a monitor structure in the channel of the microfluidic device and passing the fluid over the monitor structure. The monitor structure generates a visual display independent of size in response to a parameter of fluid having a predetermined value.

As heretofore described with respect to independent claim 1, nothing in the Beebe et al. '872 patent shows or suggests providing a monitoring structure that generates a visual display that is independent of the size of the monitor structure in response to exposure of the parameter of a fluid having a predetermined value. In the Beebe et al., '872 patent, the optical properties of the hydrogel sensor are entirely dependent upon the size of the sensor. Consequently, it is believed that independent claim 10 defines over the cited reference and is in proper form for allowance.

Claims 11-17 and 28 depend from independent claim 10 and further define a method for monitoring the environment within a microfluidic device not shown or suggested in the prior art. It is believed that claims 11-17 and 28 are allowable as depending from an allowable base claim and in view of the subject matter of each claim.

It is noted that claims 11-17 and 28 include the additional step of immobilizing a dye in the polymer matrix of the monitor structure. The Examiner suggests that Column 11, lines 18+ of the Beebe et al. '872 patent teach a pH sensitive polymer mixture hydrogel. As such, in the Examiner's opinion, such a pH sensitive polymer mixture hydrogel reads on the claimed subject matter. However, there is nothing in the '872 patent that shows or suggests immobilizing a dye within a hydrogel or that shows or suggests that a pH sensitive hydrogel that changes colors in response to a change in pH. More specifically, the pH sensitive hydrogel disclosed in the '872 patent merely changes size in response to a change in pH. Referring to Column 12, lines 62-65

of the '872 patent, describes the ability of the pH sensor to contract and expand in response to changes in pH. Hence, it is believed that dependent claims 11-17 and 28 clearly define over the cited reference.

Referring to claim 18, a method is provided for monitoring an environment within a microfluidic device. The method includes the steps of mixing a dye in a prepolymer mixture and providing the same as a pregel. Thereafter, the pregel is injected into a channel of a microfluidic device and polymerized in the channel to form a monitor structure. The fluid is passed over the monitor structure in the channel such that the dye changes color in response to a parameter of the fluid having a predetermined value.

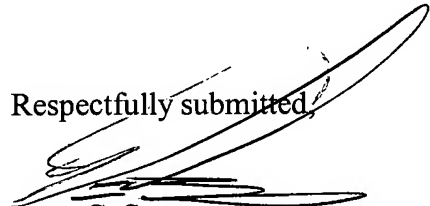
As heretofore described with respect to dependent claims 11-17 and 28, nothing in the Beebe et al., '872 patent shows or suggests the steps of mixing a dye into a prepolymer mixture and injecting the prepolymer mixture into a channel of a microfluidic device to be polymerized. Such a methodology is entirely absent from the Beebe et al., '872 patent which merely provides for a responsive hydrogel that expands and contracts to exposure of a predetermined parameter of a fluid such as pH. Consequently, it is believed that independent claim 18 defines over the cited reference and is in proper form for allowance.

Claims 19-27 depend either directly or indirectly from independent claim 18 and define a method not shown or suggested in the prior art. It is believed that claims 19-27 are allowable as depending from an allowable base claim and in view of the subject matter of each claim.

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Inventors: David J. Beebe et al.
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Applicant believes that the present application with claims 1-7 and 9-28 is in proper form for allowance and such action is earnestly solicited. The Applicant believes that there are no fees associated with this Response, however, the Director is authorized to charge payment of any other fees associated with this communication or credit any overpayment to Deposit Account No. 50-1170.

Respectfully submitted,


Peter C. Stomma
Registration No.36,020

Dated: 7/27/04

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	First Named Inventor	David J. Beebe et al.	
	Group Art Unit	1743	
	Examiner Name	Lyle Alexander	
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ENCLOSURES (check all that apply)

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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

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